



# Specification

4.80659.0000 Sodium hydroxide solution 25% low iron EMPROVE® EXPERT

	Specification	
Assay (total alkalinity calc. as NaOH)	24.8 - 25.2	%
Identity	passes test	
Appearance of solution	passes test	
Carbonate (as Na <sub>2</sub> CO <sub>3</sub> )	≤ 0.6	%
Chloride (Cl)	≤ 50	ppm
Sulfate (SO <sub>4</sub> )	≤ 30	ppm
Al (Aluminium)	≤ 10	ppm
Fe (Iron)	≤ 1.0	ppm
Residual solvents (ICH Q3C)	...excluded by production process	
Parameter with periodic testing	Specification	
Endotoxins	≤ 2.0	I.U./ml

Filtered with 0.2 µm

This product has been manufactured from Sodium hydroxide pellets Ph Eur, BP, JP, NF and water for injection USP. Water for injection USP has been prepared for this product by using purified water according to Ph Eur.

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (\*).

Dr. Nina Hegmann

Responsible laboratory manager quality control

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